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INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 6 : A61B 17/12

A1

(11) International Publication Number: **WO 00/06031**

(43) International Publication Date: 10 February 2000 (10.02.00)

(21) International Application Number: PCT/US99/17367

(22) International Filing Date: 30 July 1999 (30.07.99)

(30) Priority Data:
09/126,963 31 July 1998 (31.07.98) US

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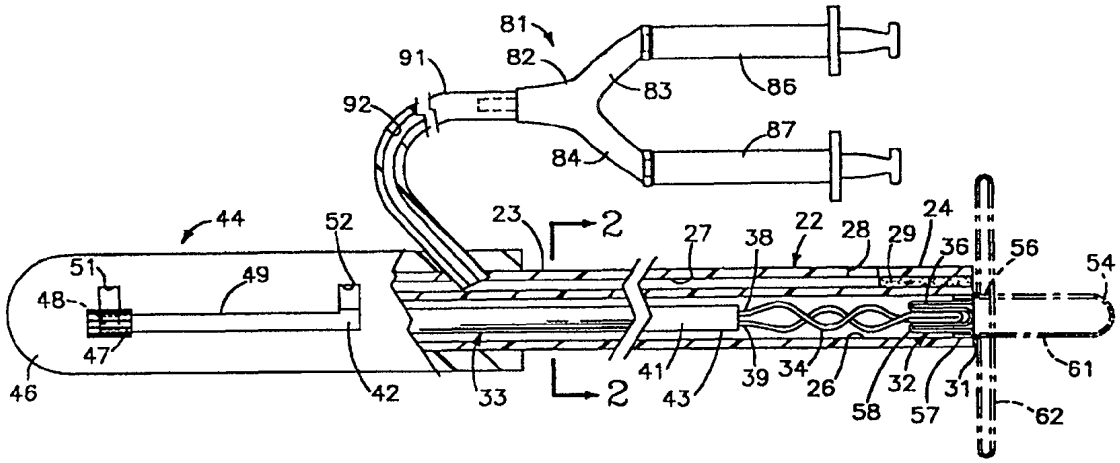
(81) Designated States: AE, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, UZ, VN, YU, ZA, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SL, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).

Published
With international search report.

(54) Title: EXPANSILE DEVICE FOR USE IN BLOOD VESSELS AND TRACTS IN THE BODY AND METHOD



(57) Abstract

This invention is a device (21) for expansion within a blood vessel having a wall defining a lumen in the body. The device (21) comprises a first elongate tubular member (22), an expansile member (309), a deformable membrane (36), a deployment mechanism (33), and a biological sealant introducer (81). The introducer (81) includes a second tubular member (111), wherein the first elongate tubular member (22) is carried by the second tubular member (111).

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EXPANSILE DEVICE FOR USE IN BLOOD VESSELS AND TRACTS IN THE BODY AND METHOD

This invention relates to an expansile device for use in vascular and non-vascular tracts in the human body and method and more particularly for percutaneous occlusion of vascular access sites in the human body.

Percutaneous access to the blood vessels and organs of the human body for diagnosis and treatment of disease processes has heretofore been accomplished. Percutaneous vascular procedures are performed involving the coronary, peripheral and cerebral vasculature. These procedures include coronary and peripheral angiography, angioplasty, atherectomies, coronary retroperfusion and retroinfusion, cerebral angiograms, treatment of strokes, cerebral aneurysms and the like. Patients undergoing such procedures are often treated with anti-platelet drugs, anticoagulants such as heparin, thrombolytics, or a combination thereof, all of which interfere with coagulation making it more difficult for the body to seal a puncture site. Various devices and methods have heretofore been utilized, however, they all have had deficiencies, including the use of complicated devices and methods. In addition, difficulties are still encountered in obtaining good seals. There is therefore a need for a device and method for percutaneous access and occlusion of vascular access sites and other puncture sites and natural tracts in the human body which overcome the deficiencies of prior art devices and methods.

In general, it is an object of the present invention to provide a closure device and method for percutaneous access and occlusion of vascular access sites, other puncture sites and natural tracts in the human body which

will make possible a positive seal of the puncture site or tract promoting rapid healing of the puncture site or tract.

Another object of the invention is to provide an expansile device and method of the above character in conjunction with which a solid biological sealant is used by introduction into the puncture site or natural tract.

Another object of the invention is to provide an expansile device and method of the above character which permit placement of the device and biological sealant without requiring measurement, sizing, or dilation of the tissue tract.

Another object of the invention is to provide an expansile device and method of the above character wherein a sealant placement member is utilized for advancing said sealant into the body and placing the sealant external to the lumen of the vessel.

Another object of the invention is to provide an expansile device and method of the above character which provides a capsule or casing for compressing and delivering a solid sealant into the body and placing the sealant external to the lumen of the vessel.

Additional objects and features of the invention will appear from the following description in which the preferred embodiments and the methods using the same are described in conjunction with the accompanying drawings.

Figure 1 is a side-elevational view partially in section of a closure device for obtaining percutaneous access and occlusion of puncture sites in the human body

incorporating the present invention and having closure means in a de-deployed or retracted position.

Figure 2 is a cross-sectional view taken along the line 2-2 of Figure 1.

Figure 3 is a side-elevational isometric view of the distal end of the device shown in Figure 1 with the closure means in a deployed or extended position.

Figure 4 is a cross-sectional view taken along the line 4-4 of Figure 3 and shows the manner in which a seal is formed with respect to a puncture.

Figures 5A-5D are cartoons demonstrating the method of using the device of the present invention for occluding a vascular access or puncture site.

Figure 18 is a side-elevational view partially in section of another embodiment of the closure or expansile device incorporating the present invention.

Figure 19 is a side-elevational view partially in section of the distal end of the device of Figure 18 with the expansile assembly in an free or expanded position without the covering membrane.

Figure 33 is a side-elevational view partially in section of another embodiment of the closure or expansile device incorporating the present invention.

Figures 34A-C are cartoons demonstrating the method of using the device of Figure 33 for occluding a vascular access or puncture site.

Figure 35 is a side-elevational view partially in section of another embodiment of the closure or expansile device incorporating the present invention.

Figures 36A-C are cartoons demonstrating the method of using the device of Figure 36 for occluding a vascular access or puncture site.

In general, the closure device of the present invention is used for the percutaneous occlusion of a puncture site and natural tract in the human body. The human body has an outer layer of skin and inner layers of tissue surrounding a blood vessel having a lumen therein defined by a vessel wall. A puncture site traverses these layers and, in the case of a vascular access puncture, the vessel wall. The closure device comprises a flexible elongate tubular member having proximal and distal extremities, an outer diameter and extending along a longitudinal axis. The flexible elongate tubular member has a first lumen extending therethrough from the proximal extremity to the distal extremity. A closure assembly is carried by the distal extremity and includes a closure mechanism and an impermeable membrane at least partially covering the closure mechanism. Deployment means carried by the proximal extremity of the flexible elongate tubular member are adapted to be operated by the human hand. The deployment means extends through the flexible elongate tubular member, includes a push-pull wire and is coupled to the closure assembly for moving the closure assembly from a de-deployed or contracted position for introduction into and through a puncture to a deployed position for forming a seal occluding the puncture.

More specifically, as shown in Figures 1-4, the closure device 21 of the present invention for percutaneous occlusion of puncture sites and natural

tracts consists of a flexible elongate tubular member 22 formed of a suitable plastic material such as polyethylene or polyurethane or polyimide. The flexible elongate tubular member 22 has a longitudinal axis and proximal and distal extremities 23 and 24. The flexible elongate tubular member 22 is provided with a main circular in cross-section first lumen 26 which may be centrally disposed extending from the proximal extremity 23 to the distal extremity 24. It is also provided with an additional or second lumen 27 which may be crescent-shaped as shown in cross-section in Figure 2 extending from the proximal extremity 23 to the distal extremity 24 where it opens through an external port 28. A plug 29 of a suitable material such as plastic is placed in the lumen 27 to occlude the lumen 27 distal of the port 28.

The flexible elongate tubular member 22 is of a suitable size, as for example a diameter ranging from 1-9 French corresponding to an outside diameter ranging from approximately .3 to 3.0 millimeters. The flexible elongate tubular member has a suitable length as for example 15-30 centimeters with the external port 28 being disposed a suitable distance adjacent to and proximal of the closure assembly 32, as for example from 1-10 millimeters up to several centimeters. The first lumen 26 may have an inside diameter ranging from .015" to 0.080", preferably .020"-.030" while the second lumen 27, if crescent-shaped may have a long axis dimension of approximately 0.015" to 0.080".

Closure means in the form of a closure assembly 32 is carried by the distal extremity 24 of the flexible

elongate tubular member 22 and is coupled or secured to deployment means or mechanism 33 for movement from a contracted, retracted or de-deployed position to an expanded or deployed position. The closure assembly 32 includes a closure mechanism 34 and an impervious membrane 36 which covers the closure mechanism 34. The closure mechanism 34 as shown in Figures 3 and 4 is in the form of a complex geometrical configuration, as for example a coil, when in a free state. The coil 34 is formed of a suitable material which can be elongated without permanent deformation but when freed or unconstrained has a substantial portion thereof which will return to a generally planar or disk-like configuration to which it has been annealed. One material found to be particularly suitable for such an application is a super-elastic or shape memory element as formed of a nickel/titanium alloy, often called Nitinol. The coil 34 has a plurality of generally circular turns 37 and has first and second ends 38 and 39 secured to the deployment mechanism 33 in a manner hereinafter described. The turns 37 of the coil 34 lie in a single plane which is generally perpendicular to the longitudinal axis of the flexible elongate tubular member 22.

The coil 34 has a diameter which is selected to overlap a puncture site as hereinafter described to occlude the puncture site. Typically, a suitable diameter such as 3 to 7 millimeters and preferably approximately 5 millimeters is used. In the de-deployed configuration the constrained coil 34 has a suitable diameter ranging from .1 mm to 3.0 mm. The coil 34 can be formed of wire having

a diameter ranging from 0.002" to 0.004" (.05 to .1 millimeters) and preferably about 0.003" (.076 millimeters). Alternatively, it can be formed of ribbon generally rectangular in cross-section and can have a thickness of approximately 0.001" to 0.002" (.025 to .05 mm.) and a width of approximately 0.003" to 0.005" (.076 to .13 millimeters).

The deployment means or mechanism 33 consists of a push-pull wire 41 which is slidably disposed in and extending through the first or main lumen 26 and has proximal and distal extremities 42 and 43. The push-pull wire 41 is formed of a suitable material such as stainless steel and has a suitable diameter as for example 0.005" to 0.032". Means is provided for securing the two ends 38 and 39 of the coil 34 to the distal extremity 43 of the push-pull wire 41 and consists of solder forming joints or adhesively bonded joints. As shown in Figure 1 the proximal end 42 of the push-pull wire 41 extends out of the proximal extremity 23 of the flexible elongate tubular member 22 and is operatively connected to a handle assembly 44 as hereinafter described.

The handle assembly 44 is formed of a body 46 of suitable material such as plastic and is mounted on the proximal extremity 23 of the flexible elongate tubular member 22. The handle 44 is sized so it is adapted to be grasped by the human hand and is provided with means for operation of the push-pull wire 41 which includes a button 47 adapted to be engaged by a finger of the hand holding the handle. The button 47 is mounted on a protrusion 48 which is slidably mounted in a longitudinally extending

slot 49 in the handle 44 and is movable between first and second positions for deploying the coil 34 from a retracted or contracted elongate position constrained within the flexible elongate tubular member 22 to an expanded position outside of the tubular member 22. The proximal extremity 42 of the push-pull wire 41 is secured to the protrusion 48 in a suitable manner such as a wire clamp or adhesive (not shown). The slot 49 opens into sideways extending notches 51 and 52 provided in the body which can receive the protrusion 48 in either the first or second position to retain the push-pull wire 41 in the desired position as hereinafter described.

The closure means 32 also includes a flexible impermeable membrane 36 which is carried by and secured to the distal extremity 24 of the flexible elongate tubular member 22. It is desired that this membrane 36 be very flexible and it therefore has a wall thickness ranging from 0.0005" to 0.010" (.0127 to .076 millimeters) and preferably 0.001" (.025 millimeters). It can be formed of any suitable flexible impermeable material such as elastomeric and non-elastomeric materials. For example, latex or silicone have been found to be suitable. The membrane 36 should be substantially impermeable to blood and other liquids. It is preferably formed as a tubular sock which can have an elongate generally cylindrical configuration with one closed end 54 and the other end circumscribed by an opening 56 which is defined by a rim 57 of the impermeable membrane. This rim 57 is circumferentially secured to the distal extremity 24 in a suitable manner such as by an adhesive (not shown) and

preferably interiorly within the first or main lumen 26. However, if desired, the rim 57 can also be affixed exteriorly to the outer surface of the tip 31 of the distal extremity 24 of the flexible elongate tubular member 22. The impermeable membrane 36 is formed in such a manner so that it can, upon manufacture of the device 21, be disposed internally of the distal extremity 24 of the flexible elongate tubular member 22 and be folded inwardly with folds 58 in the main lumen 26 to accommodate closure mechanism 34 in a constrained, retracted or contracted or de-deployed position as shown in Figure 1. It also has the flexibility of being moved outwardly by operation of the push-pull wire 41 to the sock-like dotted line position 61 shown in Figure 1.

The impermeable membrane 36 also can be caused to assume a disk-like planar configuration as shown by the dotted-line position 62 in Figure 1. This is accomplished by operation of the deployment mechanism 33 to move the push-pull wire 41 distally to urge the closure mechanism 34 distally to move out of the lumen 26 into the dotted-line position 61. As soon as the closure mechanism 34 is clear of the main lumen 26, it will expand into its memorized configuration. As this expansion is occurring, the membrane 36 covering the coil 34 is caused to move from the sock-like configuration 61 to the disk-like circular configuration 62 so that the membrane 36 is disposed on opposite sides of the closure mechanism 34 and lies in generally parallel planes which are generally perpendicular to the longitudinal axis of the flexible elongate tubular member 22 for percutaneously occluding a

puncture as hereinafter described. The deployed closure mechanism 34 is sufficiently rigid so as to provide a supporting framework for the membrane 36.

The closure device 21 also consists of biological sealant introducer means 81 carried by the handle 44 and the flexible elongate tubular member 22 for introducing a biological sealant into a puncture proximal of the closure assembly 32 after the closure assembly 32 has been positioned. The biological sealant is of a suitable type such as a two-component fibrin glue, thrombin, fibrin, collagen-thrombin, collagen, Avitene (trademark), Gelfoam (trademark), cellulose, gelatin, and mixtures or slurries thereof. It should be appreciated that other biological sealants or pharmacological agents may also be introduced into a puncture utilizing this device.

The biological sealant introducer means 81 can consist of a fitting of a suitable type such as a wye adapter 82 which is provided with first and second arms 83 and 84 with first and second syringes 86 and 87 removably mounted thereon on and containing the two separate constituents of fibrin glue being used as the biological sealant. The fitting 82 is connected to a flexible tubular member 91 which is sealed into the handle 44 and is provided with a lumen 92 therein in communication with the lumen (not shown) of the arms 83 and 84. The distal end of the flow passage 92 in the tubular member 91 is aligned to be in communication with the second lumen 27 of the flexible elongate tubular member 22 so that when the syringes 86 and 87 are operated the biological sealant components are

mixed and pass through the flow passage 92 existing via the external port 28 of the second lumen 27.

Operation and use of the device 21 in performing the method of the present invention in the percutaneous access and occlusion of vascular access sites and other puncture sites in the human body may now be described in conjunction with the cartoons shown in Figures 5A-5D. Let it be assumed that a percutaneous femoral arterial catheterization is to be performed. After sterile preparation, a thin-walled hollow needle with syringe (not shown) is percutaneously inserted through the skin 101, the underlying subcutaneous tissue 102 and then through the wall 103 defining the lumen 104 of a vessel 107 such as the femoral artery to form a puncture 106. Intra-arterial access is confirmed by the aspiration of arterial blood. A flexible wire (not shown) is then passed through the needle into the artery 107 and the needle is removed, leaving only the wire in place in the puncture 106. A vessel dilator (not shown) with a shorter conventional over-lying sheath 111 is passed over the wire through the puncture 106 into the lumen 104 after which the wire and dilator are removed. The sheath 111 extends from outside the patient through skin 101 and subcutaneous tissues 102 and through the wall 103 into the lumen 104 as shown in Figure 5A. Various diagnostic and therapeutic catheters and other similar medical devices can be passed through the sheath 111, whose diameter can range from 3 to 24 French, to perform desired procedures, as for example an angioplasty procedure during which time anti-coagulants such as heparin have been introduced. At the conclusion

of any such procedure, such instruments are removed leaving only the sheath 111 in place.

Let it be assumed that it is now desired to seal the puncture 106. The closure device 21 of the present invention with the closure assembly 32 in the retracted position as shown in Figure 1 is inserted into the sheath 111 while maintaining standard sterile precautions. The distal extremity 24 of the flexible elongate tubular member 22 is passed through the sheath 111 and into the lumen 104 so that it extends a short distance up to several inches beyond the distal extremity of the sheath 111 as shown in Figure 5A. The sheath 111 is then slowly, incrementally withdrawn proximally while maintaining the device 21 as stationary as possible. As can be seen from Figure 5B, the flexible elongate tubular member 22 has a length so that the sheath can be removed from the puncture 106 while retaining the distal extremity 24 in the lumen 104 and without removing the handle 44. When the sheath 111 has been withdrawn as shown in Figure 5B, the closure assembly 32 may be deployed by operation of the deployment mechanism 33. Alternatively, the distal extremity 24 of the flexible elongate tubular member 22 can be passed into the lumen 104 a slightly greater distance, the device 21 deployed with the sheath 111 still in position, and then both the sheath 111 and device 21 slowly withdrawn so that the sheath 111 is removed from the lumen 104 with the deployed device 21 appropriately positioned in the lumen 104.

Before deployment of the closure assembly 32, the finger button 47 is in its most proximal-most position

with the protrusion 48 being seated in the notch 51 as shown in Figure 5A. Now let it be assumed that it is desired to move the closure assembly 32 from a contracted or retracted position where it is disposed within the first main lumen 26. When it is desired to move the closure assembly 32 to an expanded or open position, the button 47 is retracted from the notch 51 and slidably advanced along the slot 49 to push the distal extremity 43 of the push-pull wire 41 distally to cause the Nitinol closure mechanism 34 to be advanced distally and to carry the folded impermeable membrane 36 out of the first or main lumen 26 to cause it to assume a sock-like shape as shown in position 61 in Figure 1. Continued forward movement of the finger button 47 causes further longitudinal movement of the push-pull wire 41 which causes further distal movement of the closure mechanism 33 until it clears the first lumen 26 so that it is substantially free to cause it to expand into its super-elastic or shape memory form of a coil to carry with it the flexible impervious membrane 36 to assume the disk-like configuration represented by position 62 as shown in Figures 1 and 4. The finger knob is then positioned so that the protrusion 48 is seated in the notch 52.

After the closure mechanism has been fully deployed, the handle 44 can be utilized to gradually retract the flexible elongate member 22 to ensure that the proximal surface of the flattened flexible membrane 36 is brought into close engagement with the inner surface of the wall 103 forming the lumen 104 in which the closure assembly 32 is disposed. This forms a liquid tight seal between the

closure assembly 32 and the wall 103 immediately adjacent the puncture 106 which in turn enables accurate and effective deposition of the biological sealant into the puncture 106 as hereinafter described. Such a liquid tight seal is also necessary in connection with the present invention to prevent the leakage of blood through the puncture 106. This serves to prevent blood from interfering with attempts to safely and permanently occlude and seal the puncture 106 and to prevent inadvertent intravascular deposition of sealant.

The formation of a good seal between the occlusion assembly 32 and the wall 103 of the vessel 107 can be ascertained in several ways. By way of example the absence of arterial blood in the puncture 106 serves to verify that a good seal has been made. Attempts to aspirate blood from the second lumen 27 with no blood return therefrom also indicates accurate placement of the device 21. Alternatively, fluoroscopy can be utilized to check the position of the closure assembly 32. This is made possible because of the radio opacity of the closure mechanism 34. Radio opaque dyes may also be utilized to ascertain whether the puncture has been effectively sealed. A small amount of radio opaque dye may be injected into the subcutaneous tissue adjacent the puncture 106. If fluoroscopy demonstrates intravascular dye then there is inadequate placement of the closure assembly 32. If perchance there is any leakage, the button 47 can be engaged by the finger and retracted out of the notch 52 and proximally for a slight distance and then moved distally to re-deploy the mechanical

assembly 32, thereafter grasping the handle 44 and pulling the flexible elongate member 22 proximally to again reestablish a seal with the wall 103 adjacent the puncture 106.

As soon as it has been established that a good seal has been formed in the manner hereinbefore described between the closure assembly 32 and the wall 103 adjacent the puncture 106, a biological sealant to be utilized can be introduced into the puncture 106 to provide a sealant 116 which extends throughout the puncture 106 from immediately outside the vessel 107 up to as far as the outer surface of the skin 101 as shown in Figure 5C. It should be appreciated, however, that it may not be necessary to introduce an amount of sealant so great as to cause it to extend proximally to the skin. Assuming that the biological sealant is a fibrin glue supplied in two ports in the syringes 86 and 87, the physician utilizing the closure device 21 while holding the handle 44 in one hand utilizes the other hand to operate the syringes 86 and 87 to cause the constituents of the biological sealant to be introduced into the wye adapter 82 where they are mixed with each other and introduced through the tubular member 91 and into the second lumen 27, thence through the exit port 28 which is adjacent the closure assembly 32. It should be appreciated that in addition to holding the handle 44 in order to maintain engagement of the closure assembly 32 with the vessel wall 103, any suitable device by way of example a pin-vise may be applied to the flexible elongate tubular member 22 immediately adjacent the skin 101 so that the engagement is maintained and the

physician has a free hand. The fibrin glue seals the innermost tissue layers in the puncture 106 and then, as hereinbefore described, can backfill the puncture 106 through the subcutaneous tissue 102 and to the skin 101, surrounding the distal extremity 24 of the flexible elongate tubular member 21 as shown in Figure 5C. If necessary, the completion of this backfilling can be observed by the fibrin glue exiting from the puncture 106. As soon as this occurs, the physician terminates further movement of the syringes 86 and 87 and then while still holding the handle 44 to retain the closure assembly 32 in place, permits the fibrin glue to set up or cure within the puncture 106 for a period of time suitable to permit the fibrin glue to form a sticky adherent clot in the puncture 106 but to prevent the fibrin glue forming a clot which is too firm so as to preclude easy withdrawal of the closure device 21. Typically this ranges from a period of time of 30 seconds to 15 minutes and preferably a period of time of approximately 1-2 minutes. The aforementioned biological sealants only adhere to collagen-containing tissues which prevents them from bonding to the flexible elongate tubular member 22. As soon as the physician determines that the fibrin glue has assumed the desired state, the button 47 carried by the handle 44 is engaged by the finger of the physician's hand and moved out of the slot 52 and then retracted proximally in the slot 49 to cause proximal movement of the push-pull wire 41 to cause a gradual straightening of the closure mechanism 34 to bring it substantially within the interior of the lumen 26 thereby permitting collapse of the flexible membrane 36 so

that it can assume a generally sock-like configuration. Thus as soon as the button 47 has been moved to its most proximal position and moved into the notch 51, the closure device 21 can gently be pulled from the seal 116 provided in the puncture 107. The hole (not shown) left in the sealant 116 after withdrawal of the flexible elongate tubular member 22 and the membrane 36 carried thereby closes on itself due to the sufficiently gel-like state of the fibrin glue or other agent. Thereafter, the site of the puncture 106 is observed to ascertain whether or not bleeding is occurring therefrom. An excellent biological seal is formed with nothing remaining at the puncture site except for the biological sealant which within a relatively short period of time as for example 1-2 weeks will be absorbed by the body.

From the foregoing it can be seen that there has been provided a closure device and a method for utilizing the same which makes it possible to quickly and efficaciously close the puncture which has been made necessary for performing a desired medical procedure as for example an angioplasty procedure. An excellent seal is formed even though anticoagulants have been introduced into the blood of the patient during the procedure to prevent the formation of clot. The application of fibrin glue in this manner permits the formation of a good clot to seal the puncture without danger of re-bleeding occurring.

It also should be appreciated that during this procedure in performing the closure of the puncture site, blood can continue to flow substantially unimpeded through the lumen 104 of the vessel. This lack of obstruction is

made possible because of the small size of the distal extremity of the closure device 21 and also because of the small size of the closure assembly 32 carried by the distal extremity 24 of the device 21. When the closure assembly 32 is deployed as hereinbefore described, it has a relatively small diameter in comparison to the size of the lumen into which it is introduced. In addition it has a flat planar configuration which, when brought into engagement with the inner surface of the wall 103, is substantially flush with the inner surface of the wall 103. Even when the closure assembly 32 is being de-deployed it occupies very little space as it is being withdrawn.

Another embodiment of an expansile or closure device incorporating the present invention is shown in Figures 18-19. The device 301 shown therein consists of a first elongate tubular member 302, preferably a flexible elongate tubular member 302, formed of a suitable plastic material, preferably a cast thermoset material such as polyimide. The first flexible elongate tubular member 302 has proximal and distal extremities 303 and 304 with a longitudinal axis extending from the proximal 303 to the distal extremity 304 and is provided with a first lumen 306 circular in cross-section which, as shown, may be centrally disposed extending from the proximal extremity 303 to the distal extremity 304. Both the outer and inner surfaces of the polyimide member 302 may be coated with a lubricious material such as Teflon™. Alternatively, the thermoset material may be a polyimide-Teflon™ or polyimide-Nylon-Teflon™ composite in order to provide the

desired lubricious inner and outer surfaces. The first flexible elongate tubular member 302 has an outside diameter ranging from approximately .008" to .050", preferably approximately .018". The first flexible elongate tubular member 302 has a suitable length as for example 10-150 centimeters. The first lumen 306 in the first flexible elongate tubular member 302 may have an inside diameter of approximately .003" to .030", preferably .012".

Expansile means in the form of an expansile assembly 307 is carried by the distal extremity 304 of the first flexible elongate tubular member 302 and is movable between contracted and expanded positions. A deployment mechanism 308 is carried by the proximal extremity 303 of the first flexible elongate tubular member 302 and adapted to be operated by the human hand for movement from a contracted position to an expanded or deployed position.

The assembly 307 includes a expansile member 309 and a membrane 311 which covers the expansile member 309. The expansile member 309 as shown in Figure 19 is in a form having a complex geometrical configuration, preferably a helical coil configuration 312, when in a free state. The helical coil 312 is formed of a suitable material, preferably Nitinol, which can be elongated or constrained without permanent deformation but, at body temperature, when freed or unconstrained returns to the helical coil configuration to which it has been annealed. The helical coil 312 has a plurality of generally circular turns creating, preferably, a proximal turn 313, a middle turn 314 and a distal turn 316. The proximal, middle and

distal turns 313, 314, 316 are generally nonplanar with respect to one another. The proximal and distal turns 313 and 316 each lie in a plane that is generally parallel to one another and generally perpendicular to the longitudinal axis of the first flexible elongate tubular member 302. The middle turn 314 is non-planar and helical as it connects the proximal and distal turns 313 and 316 so that the unconstrained helical coil configuration assumes a bi-conical shape.

The middle turn 313, when freed or unconstrained, has a suitable diameter ranging from 2 to 10 millimeters and preferably 4 to 6 millimeters is used. As hereinafter described, during deployment the middle turn 313 is partially flattened and constrained by the membrane 311 to assume a diameter ranging from 1 to 10 millimeters, preferably 11 French, in order to overlap a puncture site to assist in occluding the puncture site. The proximal and distal turns 313 and 316 are of approximately equal size and diameter ranging from 1 to 5 millimeters, preferably 2 to 3 millimeters. The unconstrained helical coil 312 configuration has a distance from the proximal 313 to the distal turns 316 of approximately 3 to 15 millimeters, preferably 5 to 8 millimeters. In the de-deployed configuration the helical coil 312 is retracted into the first flexible elongate tubular member 302 and has a contracted, constrained diameter corresponding to the approximate diameter of the Nitinol wire used to construct the expansile mechanism 309, ranging from 0.002" to 0.010", preferably .005" to .006". The distal tip of the Nitinol wire corresponding to the free end of the

distal turn 316, preferably, carries an enlargement, as for example a small ball or flattened tip 310 so as to prevent puncture of the membrane 311 by the wire during operation of the device and so as to decrease friction of the tip 310 against the wall of the lumen 306 of the first flexible elongate tubular member 302 out of which the expansile mechanism 309 is pushed as hereinafter discussed. The ball 310 may be formed by a suitable method such as arc welding, soldering, applying a polymer to the wire or folding the tip of the wire.

The deployment means or mechanism 308 includes a push-pull element or member 317 preferably in the form of a wire 317, with proximal and distal extremities 318 and 319 which is slidably disposed in and extending through the first or main lumen 306. The push-pull element 317 is formed of a suitable material such as stainless steel and has a suitable diameter as for example from .005" to .030", preferably .010". The expansile member 309 and the push-pull element 317 may be separately constructed and subsequently joined together utilizing one of several different methods. The two may be bonded or soldered together. Preferably, in order to provide for optimal torque, the stainless steel wire 317 is ground to provide a tapered portion 317a formed on the distal end 319. The tapered portion 317a is inserted into one end of an elongate member, often called a hypotube 320 made of an appropriate material such as stainless steel and adhesively bonded therein using an appropriate adhesive 325 such as Loctite™. The proximal end 318 of the Nitinol wire expansile member 309 is similarly inserted and bonded

into the opposite end of the hypotube 320. The stainless steel hypotube 320 may be of an appropriate length, such as from 2 to 15 cm, preferably 4.5 cm. It may have an outer diameter ranging from .005" to .030", preferably .010" and an inner diameter ranging from .003" to .010", preferably .006".

Alternatively, both the push-pull wire 317 and the expansile mechanism 309 can be formed from a single piece of Nitinol wire in which case, in order to provide optimal pushability, torquability and column strength of the push-pull wire 317, two alternative techniques are utilized. First, a Nitinol wire diameter of approximately .010" is used by grinding down the distal end 319 to a diameter suitable for subsequent formation of the expansile member 309.

A second technique utilizes a Nitinol wire having a diameter suitable for formation of the expansile mechanism 309. In such case, the push-pull wire 317 is covered with a suitable polymer jacket, preferably made of polyimide and having an diameter of approximately .005" to .0101". The polymer jacket is thicker at the proximal end 318, necked down at the distal end 319 of the push-pull wire 317 and secured to the push-pull wire 317 at distal and proximal ends by a suitable adhesive such as Loctite™.

As shown in Figure 18 the proximal end 318 of the push-pull wire 317 extends out of the proximal extremity 303 of the first flexible elongate tubular member 302 so that the deployment means can be operated by the human hand as hereinafter described.

It should also be appreciated that push-pull elements or mechanisms, other than a push-pull wire, can be utilized to deploy and de-deploy the expansile member and the expansile assembly.

A stop mechanism or means 321 is provided to control the range of movement or travel of the push-pull wire 317 during deployment and de-deployment of the expansile assembly 307. The stop mechanism 321 comprises first and second, slidable nested or coaxially mounted stop tubes 322 and 323 formed of an appropriate material such as plastic or stainless steel. The distal end of the first stop tube 322 carries a bushing 324. The bushing 324 is secured to the distal end of the first stop tube 322 by suitable means such as an adhesive (not shown). The proximal end 318 of the push-pull element 317 is affixed to the first tube by suitable means such as an adhesive. The push-pull element 317 with the first tube 322 affixed thereto and the bushing 324 carried thereby is movable longitudinally of the second tube 323 which has its distal extremity secured to the proximal extremity 303 of the elongate tubular member 302. It is movable from a forward most position with the bushing 324 in engagement with the proximal end 303 and a rearwardmost position in engagement with an annulus 326 mounted in the proximal extremity of the second tube 323 by suitable means such as an adhesive and through which the first tube 322 slidably extends. The lengths of the first and second tubes 322 and 323 are selected so that the travel between the forwardmost and rearwardmost positions ranges between 2 cm and 10 cm.

The expansile assembly 307 also includes a deformable, flexible membrane 311 which is carried by, and as shown, can be secured to the distal extremity 304 of the first flexible elongate tubular member 302 as hereinafter discussed. Since it is desired that this membrane 311 be very flexible it has a wall thickness ranging from 0.001" to 0.015" and preferably about 0.004". It can be formed of any suitable flexible material such as an elastomeric or a non-elastomeric material including latex and silicone. The membrane 311 can also be made of an impermeable or a permeable material providing for multiple uses of the device. A satisfactory membrane 311 can be made of Chemoprene™ or one of the polyurethane elastomers such as Polyblend™ having a shore hardness durometer of 30 to 70A, and preferably 55A, Tecoflex™ having a shore hardness durometer of 60 to 100A or Pellathane™ having a shore hardness durometer of 70 to 100A. Alternatively the membrane 311 can be made of multiple layers including a central Polyblend™ layer having a thickness of approximately .005" to .010" and a thin outer Tecoflex™ layer having a thickness of approximately .0005". This layered membrane 311 is made by dipping the Polyblend™ in a Tecoflex™ solution, for example a Tecoflex™ 85A solution. As shown, the membrane 311 is substantially impermeable to blood and other liquids. It is formed as a tubular sock 333 which has an elongate generally cylindrical configuration with one closed end 329 and the other end circumscribed by an opening 331 which is defined by a rim 332 of the same material. The tubular sock 333 has an appropriate length, as for example ranging from

2- 5 mm, preferably 7 mm. When the membrane 311 is made from Polyblend™, typically supplied in a tubular form and cut into lengths of appropriate dimensions with both ends open, the closed end 329 of the membrane 311 is formed by dipping one open end of the Polyblend™ into a Tecoflex™ solution, preferably 10% by weight of 85A Tecoflex™, to provide a sealing plug 327. The rim 332 of the membrane 311 can be circumferentially secured to the distal extremity 304 of the first flexible elongate tubular member 302 in a suitable manner such as by the Loctite 454™ adhesive (not shown).

A length of stainless steel hypotube 328 has one end secured to the distal end 304 of the first flexible elongate tubular member 302 (see Figure 18) using an appropriate adhesive such as Loctite 406™. The hypotube 328 has an appropriate length ranging from 2 mm to 10 mm, preferably 5 mm, and is secured to the first flexible elongate tubular member 302 and extends distally of the same by approximately 2-8 mm. The rim 332 of the membrane 311 is affixed exteriorly of the stainless steel hypotube 328 by an adhesive (not shown), preferably, distal to the point at which the hypotube 328 is secured to the first flexible elongate tubular member 302 and with the closed end 329 of the membrane 311 oriented distally thereon as shown in Figure 18. As such, a portion of the membrane 311 distal to the rim 332 overlies the steel hypotube 328 and is non-adherent thereto. It should be appreciated if desired that the rim 332 can be secured directly to the outer surface of the distal extremity 304. In either arrangement, the membrane 311 assumes a sock-like

conformation as shown in Figure 18. Alternatively, the rim 332 of the membrane 311 may be secured interiorly within the hypotube 328 or, if the hypotube 328 is not utilized, within the first or main lumen 306 of the first flexible elongate tubular member 302. In addition, the membrane 311 may be secured to the Nitinol wire proximal to the expansile member 309.

The impermeable membrane 311 of the expansile assembly 307 can be caused to assume various configurations including a planar disk-like configuration as shown by the dotted-line position in Figure 18. This is accomplished by operation of the deployment mechanism 308 to move the push-pull element 317 distally to urge the expansile member 309 distally out of the lumen 306 into the membrane 311. The operator can assist deployment by applying a slight rotation to the push-pull element 317 as it is moved distally. As soon as the expansile member 309 clears the first lumen 306, it begins to expand into its shape memory, predetermined configuration. The distal turn 316 of the expansile member 309 in the form of a coil operates to expand the membrane 311 initially to a small degree. This initial process avoids sudden gross distortion of the membrane 311. As the expansile member 309 moves distally out of the lumen 306 and expands into the membrane 311, the non-adherent portion of the membrane 311 distal to the rim 332 preferentially begins to move and assume the planar configuration because of the lubricious surface of the stainless steel hypotube 328. Expansion proceeds with the middle turn 314 forming a coil and causing the membrane 311 to expand to its desired

size, approximately 12 French. The proximal turn 313 forming a coil then centralizes and stabilizes the configuration so that the push-pull element 317 is centered with respect to the middle turn 314 and the fully expanded membrane 334. During expansion of the expansile member 309 the membrane 311 covering the coil 312 constrains the coil 312, thus exerting counteractive or countervailing contractile forces on the expanding coil 312 which is seeking its memorized, bi-conical, free shape or configuration 312. Thus, the membrane 311 does not expand passively. Rather, the expanding coil 312 forcibly expands the membrane 311 to cause the non-planar turns 313, 314 and 316 of the coil 312 to assume a substantially planar or disk-like configuration with the membrane 334 being taut and disposed on opposite sides of the expansile mechanism 309 to form an expansile assembly 307 which when expanded is generally perpendicular to the longitudinal axis of the first flexible elongate tubular member 302. The expansile mechanism 309 when deployed is sufficiently rigid so as to provide a supporting framework for the membrane 311 to keep it taut.

It should be appreciated that other embodiments may be utilized employing superelastic expansile members with various memorized configurations. In addition, as hereinbefore discussed, different membrane materials may be utilized in order to construct permeable or impermeable assemblies for different functions. The predictability of countervailing, expansile forces and resistive, membrane forces enables the construction of expansile assemblies with predetermined, deployed configurations. In addition,

instead of sliding a push-pull wire, the Nitinol member can be secured to a wire which remains stationary. In such an embodiment, the expansile member and wire are sheathed within an elongate tubular member which has a sock-like membrane secured to the distal end thereof and whence the member is deployed into the membrane by sliding the sheath proximally.

Operation and use of the device 301 is very similar to that described for the embodiment of the closure device 21 with the following differences. The expansile device 301 shown in Figures 18-19 is not used with biological sealants. Thus, after bringing the expansile assembly 307 into contact with the distal end of the puncture 106, a proximal force of tension or traction is maintained on the expansile assembly 307 for a predetermined period of time ranging from 2 minutes to several hours, preferably 30 minutes to 1 hour, until the puncture 106 is sealed. Release of the tension is followed by moving the expansile assembly 307 from the deployed or expanded position to the de-deployed or contracted position after which the device 301 may be removed as hereinbefore described.

A second difference is that the radio-opacity of the expansile mechanism 309 is determined by the configuration of the coil 312. When it is in the unconstrained, memorized, bi-conical configuration, the coil 312 is not fluoroscopically visible due to the small size of the individual turns of the Nitinol wire and the non-planar configuration. When the expansile mechanism 309 assumes the flat disk-like shape within the membrane 334 the cumulative densities of the Nitinol turns can be

fluoroscopically visualized. As hereinbefore discussed, this too is an easy method of ascertaining or confirming formation of a good seal between the expansile assembly 307 and the wall 103 of the vessel 107.

Furthermore, the low profile of the device 301 affords the ability to reenter the vessel 107 with the introducer sheath 111 if there has been inadequate occlusion and bleeding continues or other complications ensue. For example, let it be assumed that the operator believes the puncture 106 is sealed after removal of the sheath 111 and he therefore de-deploys the expansile assembly 307 as hereinbefore described. If, after so doing, he observes continued bleeding from the puncture 106, the operator can reenter the vessel 107 by releasing tension, pushing the first flexible elongate tubular member 302 distally and reinserting the sheath 111 into the vessel 107 over the first flexible elongate tubular member 302. The operator can also reenter the vessel for additional medical purposes if necessary. The same approach applies if the membrane 311 breaks or the expansile assembly 307 otherwise malfunctions. In this case the sheath 111 is replaced as hereinbefore described and the malfunctioning expansile device 301 is expeditiously replaced.

Another embodiment of an expansile device incorporating the present invention is shown in Figures 33-34. The expansile device 501 is similar to that shown in Figures 18 with the principal difference being in the biological sealant introduction means utilized in the device 501. Thus all the parts of the expansile device 301 that are present in the expansile device 501 carry the

same numbers. Solid biological sealant introducer means 502 is provided by a second elongate tubular member 503 having proximal and distal extremities 504 and 506, a longitudinal axis and first and second lumens 507 and 508 extending from the proximal extremity 504 to the distal extremity 506 of the second elongate tubular member 503. The distal extremity 506 of the second elongate tubular member 503 terminates proximal to the distal extremity 304 of the first elongate tubular member 302 and adjacent to the expansile member 309, the first elongate tubular member 302 being disposed in the second lumen 508 of the second elongate tubular member 503.

The second elongate tubular member 503 is preferably flexible and formed of a suitable plastic material, preferably an extruded Pebax™, Elf Atochem™ or other suitable thermoplastic elastomer having a shore hardness durometer of 50D or 72D. The coil or crush strength of the second elongate tubular member 503 is great enough so that it withstands the force of the grasping members 351 of the tensioning device 335 without being functionally deformed or compromised as hereinbefore described. The first elongate tubular member 302 is retained and fixed in the second lumen 508 of the second elongate tubular member 503 by suitable adhesive means as hereinafter described.

The second elongate tubular member 503 is of a suitable size, as for example having an outer diameter ranging from .050" to .090", preferably approximately .072", a first lumen 507 having a diameter ranging from .020-.060", preferably .040", a second lumen 508 having a diameter ranging from .015-.040", preferably .020" and a

suitable length as for example ranging from 10-100 cm and preferably being approximately 30 cm.

The distal extremity 506 of the second elongate tubular member 503 carries a tip 509 having a circumference 511 at least a portion of which lies in a plane forming an angle with the longitudinal axis of the second elongate tubular member 503 which is greater than 90 degrees. This is preferably accomplished by providing the tip 509 with a bevel so that the second lumen 508 of the second elongate tubular member 503 terminates distally of the first lumen 507 of the second elongate tubular member 503, preferably 3-8 mm distally thereof as hereinafter described. As hereinbefore described, the distal extremity 506 of the second elongate tubular member 503 terminates proximal to the distal extremity 304 of the first elongate tubular member 302 and adjacent to the expansile member 309 by approximately 5-15 mm. Thus, the tip 509 terminates approximately 3-8 mm proximal to the steel hypotube 328 carried by the distal extremity 304 of the first elongate tubular member 302.

Proximal adaption for solid sealant introduction into the first lumen 507 of the second elongate tubular member 503 includes an appropriate wye hub or adaptor 521 carried by the proximal extremity 504 of the second elongate tubular member 503. The adaptor 521 is constructed of an appropriate plastic material such as machined Delrin or other acetal or polycarb material. As shown in Figure 33, a first arm or end 522 of the adaptor 521 is provided having a lumen 523 in alignment with the second lumen 508 of the second elongate tubular member 503. The first

arm 522 is also provided with a proximally extending annular ring, 524, recess or rim in alignment with the lumen 523 of the first arm 522. The proximal extremity 303 of the first elongate tubular member 301 extends proximally from the second lumen 508 of the second elongate tubular member 503 and thence out of the lumen 523 of the first arm 522 and into the ring 524. The second stop tube 323 of the first elongate tubular member 301 is seated within the ring 524 and secured to the adaptor 521 by appropriate adhesive means thereby forming a fluid-tight seal and fixing the first elongate tubular member 301 in relation to the second elongate tubular member 503. The first elongate tubular member 301 may also be adhesively fixed within the second lumen 508 of the second elongate tubular member 503.

A second arm or end 526 of the adaptor 521 is provided with a chamber 527 having proximal and distal ends 528 and 529. As shown in Figure 33, the proximal extremity 504 of the second elongate tubular member 503 is adhesively secured within the distal end 529 of the chamber 527 in an appropriate manner so that a fluid tight seal is formed and the first lumen 507 of the second elongate tubular member 503 is aligned with the chamber 527 of the second arm 526 of the adaptor 521. This may be accomplished by severing and removing a portion of the proximal extremity 504 of the second elongate tubular member 503 carrying the second lumen 508 so that only the portion of the proximal extremity 504 of the second elongate tubular member 503 carrying the first lumen 507 may be secured within the chamber 527 of the second arm 526 of the adaptor 521.

As shown in Figure 33, a loading chamber or casing 536 formed of an appropriate material, preferably PEBAX™ 72D clear having an inner diameter greater than the outer diameter of the portion of the proximal extremity 504 of the second elongate tubular member 503 carrying the first lumen and, preferably, approximately .045", is adhesively secured within the chamber 527 of the second arm 526 of the adaptor 521 so that, proximally, the casing 536 extends out of the second arm 526 and distally, it receives the same portion of the proximal extremity 504 of the second elongate tubular member 503 as it enters the distal end 529 of the chamber 527 in the adaptor 521.

Alternatively, the chamber 527 of the adaptor 521 may be provided with a second arm 526 having a tapered proximal end 528 as hereinafter described.

A capsule or casing 541 for containing and compressing the solid biological sealant 542 is provided and is constructed of a suitable plastic material such as PEBAX™, Elf Atochem™ or other suitable thermoplastic elastomer having a shore hardness durometer of 72D. The capsule 541 is sized so as to be capable of being introduced into and retained in the casing 536 in the proximal end 528 of the chamber 527 in the second arm 526 of the adaptor 521 so that the solid biological agent 542 can be extruded out of said capsule 541 and adaptor 521 and into the first lumen 507 of the second elongate tubular member 503 as hereinafter described. Thus, the capsule 541 has a suitable length ranging from .5" to 2", preferably 1.5", an outer diameter greater than the outer diameter of the second elongate tubular member 503 and less than the inner

diameter of the loading chamber 536 and an internal diameter being smaller than the internal diameter of the first lumen 507 of the second elongate tubular member 503, ranging from .015" to .055", preferably being .036".

The capsule 541 is loaded with solid sealant 542 prior to being introduced into the device 501. The sealant 542 is compressed and centered in the capsule 541 so that the capsule 541 extends several millimeters beyond the compressed sealant 542 at either end thereof.

As hereinafter described, the solid biological sealing agent 542 is extruded out of the capsule 541 and adapter 521 and into the first lumen 507 of the second elongate tubular member 503 by the use of a sealant placement member 561 having proximal and distal extremities 562 and 563 and a proximal hub, cap or handle 564. The placement member 561 may be in the form of a push rod or a push wire constructed of an appropriate flexible plastic or metal material.

The placement member 561 has a suitable diameter so that it is capable of being slidably disposed in the casing 536, capsule 541, adaptor 521 and first lumen 507 of the second elongate tubular member 503 as hereinafter described. The cap 564 of the sealant member 561 is constructed of an appropriate material such as Polycarb™ and is adhesively secured to the proximal extremity 562 thereof so as to prevent the sealant placement member 561 from extending distally out of the first lumen 507 of the second elongate tubular member 503 and into the artery 107 as hereinafter described. The sealant placement member 561 has a suitable length so that when fully inserted and

disposed in the first lumen 507 of the second elongate tubular member 503 the hub 564 abuts or is seated against the casing 536 in the proximal chamber 528 of the adaptor 521, thus functioning as a backstop, and the distal extremity 563 of the sealant placement member 561 terminates at or several millimeters distal of the end of the first lumen 507 of the second elongate tubular member 503.

Operation and use of the device 501 is similar to that described for the expansile device 301 except for the sealant introducer means in the device 501. As soon as it has been established that a good seal has been formed between the occlusion assembly 307 and the wall 103 adjacent the puncture the physician can introduce the solid sealant as hereinafter described and shown in Figure 34A-C.

The sealant containing capsule 541 can be loaded into the device 501 as hereinbefore described prior to the device 501 being placed into the patient or after a good seal has been established therewith. In addition, multiple capsules may be provided during sterile packaging of the device 501 permitting the physician to deploy as much sealant as is necessary to seal a puncture.

While holding the handle 564 of sealant placement member 561, the physician inserts the distal extremity 563 thereof into the capsule 541 retained in the casing 536 in the chamber 527 of the second arm 526 of the adaptor 526. Pushing the placement member 561 in a distalward direction extrudes the sealant 542 out of the capsule 541, with the capsule 541 being retained in the casing 536, and out of

the adaptor 521 into the first lumen 507 of the second elongate tubular member 503. Continued distal movement of the placement member 561, until the hub 564 thereof seats against the capsule 541, advances the compressed sealant 542 distally in the first lumen 507 and out of the first lumen 507 into the body proximal to the expansile member 309 and external to the lumen 104 of the vessel 107. The bevel on the tip 509 of the second elongate tubular member 503 permits easy, accurate and effective placement of the solid sealant 542 without buckling or folding of the same as shown in Figure 34A-C.

The remainder of the operation of the device 501 is as hereinbefore described in conjunction with use of the device 301.

Another embodiment of an expansile device incorporating the present invention is shown in Figures 35-36. The expansile device 601 is similar to that shown in Figure 33 with the principal difference being in the biological sealant introduction means utilized in the device 601. Thus, all the parts of the expansile device 501 that are present in the expansile device 601 carry the same numbers. Solid biological sealant introducer means 602 is similar to the introducer means 502 shown in Figure 33 with the principal difference being that the first elongate tubular member 302 is not fixed in relation to the second elongate tubular member 503. Rather, the second elongate tubular member 503 is slidably carried by the first elongate tubular member 302 as hereinafter described.

The second elongate tubular member 503 in device 601 is similar in construction to that in device 501 with the principal difference being that the second lumen is absent in device 601.

The second elongate tubular member 503 carries at least one, but, preferably, proximal and distal external eyes, rails or rings 603 and 604, said first elongate tubular member 302 being slidably disposed in said external eyes 603 and 604 as hereinafter described. It should be appreciated that any appropriate number of external eyes or guides may be utilized. The external eyes 603 and 604 are formed of a suitable material such as extruded Pebax™ having a similar shore hardness and are appropriately bonded to the second elongate tubular member 503, by either being thermally or adhesively bonded thereto.

The external eyes 603 and 604 are of a suitable size, as for example having outer diameters ranging from .030-.050" and inner diameters ranging from .010-.045", but in no case having inner diameters smaller than the outside diameter of the first elongate tubular member 302 and the deployment means 308 carried thereby. The external eyes 603 and 604 have lengths ranging from .5-4 centimeters.

As shown in Figure 35, the proximal eye 603 is carried at an appropriate position along the longitudinal axis of the second elongate tubular member 503 so that it can slide over, be guided by, and simultaneously support, the first elongate tubular member 302 as hereinafter described.

The distal eye 604 carries a soft beveled distal tip 611 constructed of an appropriate material such as Pebax™ having a shore hardness durometer less than that of the distal eye 604, preferably approximately 90A. The tip 611 is thermally or adhesively bonded to the distal eye 604. As shown in Figure 35, the distal eye 604 and tip 611 carried thereby are bonded to the distal extremity 506 of the second elongate tubular member 503 so that the bevel of the tip 611 and the bevel of the tip 509 of the distal extremity 506 of the second elongate tubular member 503 are contiguous and lie in the same plane, the tip 611 of the distal eye 604 thus extending distal to the tip 509 of the distal extremity 506 of the second elongate tubular member 503. The softer, distally extending tip 611 of the distal eye 604 provides for easier and smoother sliding of the second elongate tubular member 503 over the first flexible elongate tubular member 302 as hereinafter described.

It should be appreciated that the external eyes can also be constructed by starting with an extruded catheter material similar to that utilized for the device 501 and subsequently removing all of the catheter portion carrying the second lumen except for predetermined lengths thereof which form said eyes.

As shown in Figure 35, proximal adaption for solid sealant introduction into the lumen 507 of the second elongate tubular member is similar to that described in conjunction with the device 501 except for that fact that the proximal hub or adaptor 521 of device 601 is provided with a single end or arm 526. Thus, as hereinafter

described, when the first flexible elongate tubular member 302 is disposed in the external eyes 603 and 604 the deployment means 308 of the proximal extremity 303 of the first flexible elongate tubular member 302 are exposed and freely operative as hereinbefore described.

Operation and use of the device 601 is similar to that described for the expansile device 501 except as hereinafter described and shown in Figure 36A-C. The first flexible elongate tubular member 302 carrying the expansile assembly 307 may be used initially with or without the second elongate tubular member 503 and the solid sealant introduction means 602 carried thereby. If used separately, as soon as it has been established that a good seal has been formed between the occlusion assembly 307 and the wall 103 adjacent the puncture and all other sheaths are removed the physician can introduce the solid sealant as hereinafter described.

While manually maintaining proximal tension on the first flexible elongate tubular member 302 the proximal extremity 303 thereof, carrying the deployment means 308, is threaded distally to proximally through the tip 611 of the distal eye 604 and the proximal eye 603 of the second elongate tubular member 503. The second elongate tubular member 503 is pushed distally, guided by and sliding along the first flexible elongate tubular member 302 until the tip 611 of the distal eye 604 rests or abuts up against the proximal end of the hypotube 328 carried by the distal extremity 304 of the first flexible elongate tubular member 302.

The remainder of the operation of the device 601 is as hereinbefore described in conjunction with use of the device 501.

It should be appreciated that other embodiments of the present invention are contemplated. For example, in one embodiment, a substantially coaxial arrangement of first and second elongate tubular members is provided in which the first member is slidably disposed within the lumen of the second member. Solid biological sealant is compressed and loaded or contained coaxially between first and second elongate tubular members at an predetermined appropriate position along the lengths thereof. Deployment of the expansile member is followed by proximal withdrawal of the second elongate tubular member, over and off of the first flexible elongate tubular member, which exposes the sealant to the tissue tract, external to the vessel wall and adjacent to the expansile member.

It is apparent from the foregoing that there has been provided an expansile or closure device and method for percutaneous access and occlusion of punctures which medical procedures have required being placed in the human body. By varying the free shape or configuration of the super elastic alloy expansile member and the size and material of the membrane, the predetermined configuration and rigidity of the expansile assembly is varied so that it becomes possible to occlude puncture sites and natural tracts of various sizes and in various locations in the body such as laparoscopic puncture sites, pleural-cutaneous fistulas, including chest-tube puncture sites, intestinal-cutaneous fistulas, fistulas between the

intestines, biliary tract of the stomach and the like. The expansile assembly establishes the distal boundary for the puncture so that it enables accurate placement of and prevents inadvertent intravascular injection and embolization of the biological sealant. The expansile device of the present invention makes possible the use of biological sealants in which for example fibrin glue is utilized and forms a clot which has greater strength than a natural clot formed by the body. In addition it makes it possible to the bypass the natural coagulation system of the human body even though anticoagulants have been administered to the patient during the prior medical procedure or procedures. Although fibrin glue has been discussed as the principal biological sealant, other sealants may be utilized such as collagen, Avitene™ slurries, Gel Foam™, cellulose, fibrin and thrombin, collagen and thrombin mixtures, all of which are non-adherent to the expansile device. Individual components of multi-component sealants may be separately introduced into the different annular spaces of the expansile device comprising three flexible elongate tubular members. By utilizing an annular distal mixing chamber, component-to-component fluid contact is maximized. A maximized area of contact affords optimal mixing and setting of the sealant at just the site where it is needed. Furthermore, circumferential introduction of mixed biological sealant into the puncture provides better distribution. In addition, it should be appreciated that other means of sealant introduction to the flexible elongate tubular member are available. For example, a multi-component

sealant such as fibrin glue may, alternatively, be mixed prior to introduction into the flexible elongate tubular member.

Solid biological sealants may also be used, such as collagen plugs compressed and contained or retained in casings or capsules, which are capable of being introduced into and extruded from the expansile device and placed external to the vessel wall. Solid sealant introduction means are provided which do not require additional tissue tract dilation or trauma in order to accurately place solid sealant external and adjacent to the puncture in the vessel wall. Such auto-placement or auto-positioning assures accurate deposition of solid sealant with a minimum of additional procedural steps and obviates the problem of solid sealant buckling or folding as the same is advanced into position. In addition, the decision to use such introduction means may be made after the expansile member is already in place within the vessel. In such situations, solid sealant introduction means may be placed over an expansile device not initially carrying such means.

The shape of the expansile mechanism utilized in the expansile device of the present invention that abuts the inner surface of the wall through which the puncture extends enlists the normal pressure of the arterial blood flow to help retain the expansile assembly in contact with the wall. The expansile assembly is small in size and even when being deployed into the blood vessel permits substantially unobstructed blood flow through the vessel to continue during the expansile procedure thus avoiding

ischemic and thrombotic complications associated with stasis of blood. The small size similarly prevents the expansile assembly from damaging or impinging on the opposite wall of the blood vessel during deployment or de-deployment of the device.

Since the expansile device and method of the present invention does not require long term intravascular deployment of a foreign body such as collagen, intra-arterial anchors or sutures, nor does it utilize balloon technology with the attendant risks of balloon rupture or tearing, there is a greatly reduced risk of life and limb threatening infections and the introduction of particulates or air emboli into the bloodstream.

Since the occlusions which are formed in punctures utilizing the expansile device and method of the present invention can be accomplished quickly, this facilitates early ambulation of the patient and helps to avoid traditional complications such as arterio-venous fistulas, pseudo-aneurysms, thrombosis and embolism. Since the device is typically disposed of after one use, the danger of transmitting diseases to the blood stream of the patient is greatly reduced. Medical costs to the patient and to society are also thereby reduced.

Although the expansile device and method have been described principally in use with the human body it should be appreciated that the expansile device and method also can be utilized with animals in a similar manner.

In addition, it should be appreciated that the expansile device can be used within other natural tracts

in the body in order to provide for other therapeutic or prophylactic modalities.

It is apparent from the foregoing that there has been provided a expansile device and method for percutaneous access and occlusion of puncture sites in the human body that have distinct advantages over those heretofore provided.

Percutaneous methods are widespread techniques that offer less invasive, safer and more cost-effective diagnostic and therapeutic access to organs of the human body. In order to fully realize the advantages of percutaneous access however, morbidity associated with access sites must be anticipated and prevented wherever possible. Indeed, advanced therapeutic interventions have led to a greater range of access site complications. A patient who suffers such complications must often undergo a more invasive procedure in order to prevent devastating injury to life or limb. Such procedures incur additional risks and costs. Effective percutaneous occlusion of a percutaneous vascular access site that proves to be otherwise difficult to manage is a major achievement. Without such treatment many of the advantages of percutaneous diagnostic and therapeutic procedures are lost. Satisfactory solutions have heretofore been absent in the prior art. The device and method of the present invention obviate many of the morbid side effects associated with puncture sites hereinbefore described.

WHAT IS CLAIMED:

1. A device for expansion within a blood vessel having a wall defining a lumen in the body comprising a first elongate tubular member having proximal and distal extremities and having a longitudinal axis, an expansile member carried by the distal extremity of the first elongate tubular member and movable between contracted and expanded positions, said expansile member having a predetermined configuration in the expanded position, a deformable membrane at least partially covering the expansile member, said deformable membrane being sized so as to be capable of expanding as the expansile member moves from the contracted position to the expanded position, deployment means carried by the proximal extremity of the first elongate tubular member and connected to the expansile member, said deployment means being adapted to be capable of moving the expansile member between the contracted and expanded positions and means connected to said first elongate tubular member for introducing a biological sealant into the body proximal to said expansile member and external to the lumen of the vessel, said sealant introducing means including a second elongate tubular member having proximal and distal extremities, a longitudinal axis and a first lumen extending from the proximal to the distal extremity of the second elongate tubular member, the distal extremity of said second elongate tubular member terminating proximal to the distal extremity of said first elongate tubular member and adjacent to said expansile member, said first

elongate tubular member being carried by said second elongate tubular member.

2. A device as in Claim 1 further including a tip carried by the distal extremity of the second elongate tubular member, said tip having a circumference, at least a portion of said circumference lying in a plane forming an angle with the longitudinal axis of the second elongate tubular member which is greater than 90 degrees.

3. A device as in Claim 2 wherein said biological sealant introducing means includes an adaptor carried by the proximal extremity of said second elongate tubular member for introducing said biological sealant into the first lumen of said second elongate tubular member and a sealant placement member for advancing said sealant distally out of said adaptor and into the first lumen of said second elongate tubular member and placing said sealant into the body proximal to said expansile member and external to the lumen of the vessel.

4. A device as in Claim 3 wherein said sealant placement member is a push rod.

5. A device as in Claim 3 wherein said sealant placement member is a push wire.

6. A device as in Claim 3 further including a capsule for containing and compressing said biological sealant, said capsule being sized so as to be capable of being introduced into and retained in said adaptor so that said biological sealant can be extruded out of said capsule and adaptor by said sealant placement member and into the first lumen of said second elongate tubular member.

7. A device as in Claim 2 wherein said biological sealant is selected from a group consisting of: (a) fibrin glue; (b) collagen; (c) Avitene; (d) cellulose; (e) gelatin; (f) Gelfoam; (g) Surgicel; (h) thrombin; (i) fibrin; (j) thrombin-collagen.

8. A device as in Claim 3 wherein said second elongate tubular member carries a second lumen extending from the proximal to the distal extremity of the second elongate tubular member, said second lumen of the second elongate tubular member terminating distally of said first lumen of the second elongate tubular member, said first elongate tubular member being disposed in the second lumen of said second elongate tubular member.

9. A device as in Claim 3 further including at least one external eye carried by the second elongate tubular member, said first elongate tubular member being slidably disposed in said at least one external eye.

10. A device as in Claim 9 including a plurality of external eyes.

11. A device as in Claim 9 wherein said at least one external eye extends distal to the tip of distal extremity of the second elongate tubular member.

12. A method for expanding a device within a blood vessel having a wall defining a lumen in the human body, by use of a device having a first elongate tubular member having proximal and distal extremities and a longitudinal axis, an expansile member carried by the distal extremity of the first elongate tubular member and movable between contracted and expanded positions, said expansile member having a predetermined configuration in the expanded

position, a deformable membrane covering the expansile member in the expanded position, deployment means carried by the proximal extremity of the first elongate tubular member and adapted to be operated by the human hand for controlling movement of the expansile member between the contracted and expanded positions and means connected to said first elongate tubular member for introducing a solid biological sealant into the body proximal to said expansile member and external to the lumen of the vessel, said sealant introducing means including a second elongate tubular member having proximal and distal extremities, a longitudinal axis and a first lumen extending from the proximal to the distal extremity of the second elongate tubular member, the distal extremity of said second elongate tubular member terminating proximal to the distal extremity of said first elongate tubular member and adjacent to said expansile member, said first elongate tubular member being carried by said second elongate tubular member, the method comprising introducing the distal extremity of the first elongate tubular member and the expansile member carried thereby through the wall of the vessel so that the expansile member is disposed within the lumen of the vessel, moving the expansile assembly from a contracted to an expanded position and pulling the first elongate tubular member proximally to bring the expansile member into engagement with the wall in the lumen of the vessel, introducing a solid biological sealant into the second elongate tubular member after the expansile member has been broughtinto engagement with the wall of the vessel to cause the biological sealant to

surround the distal extremity of the first elongate tubular member and to substantially fill the space between the wall of the vessel and the expansile member, thereafter moving the expansile member from the expanded position to a contracted position and removing the expansile member from the biological sealant.

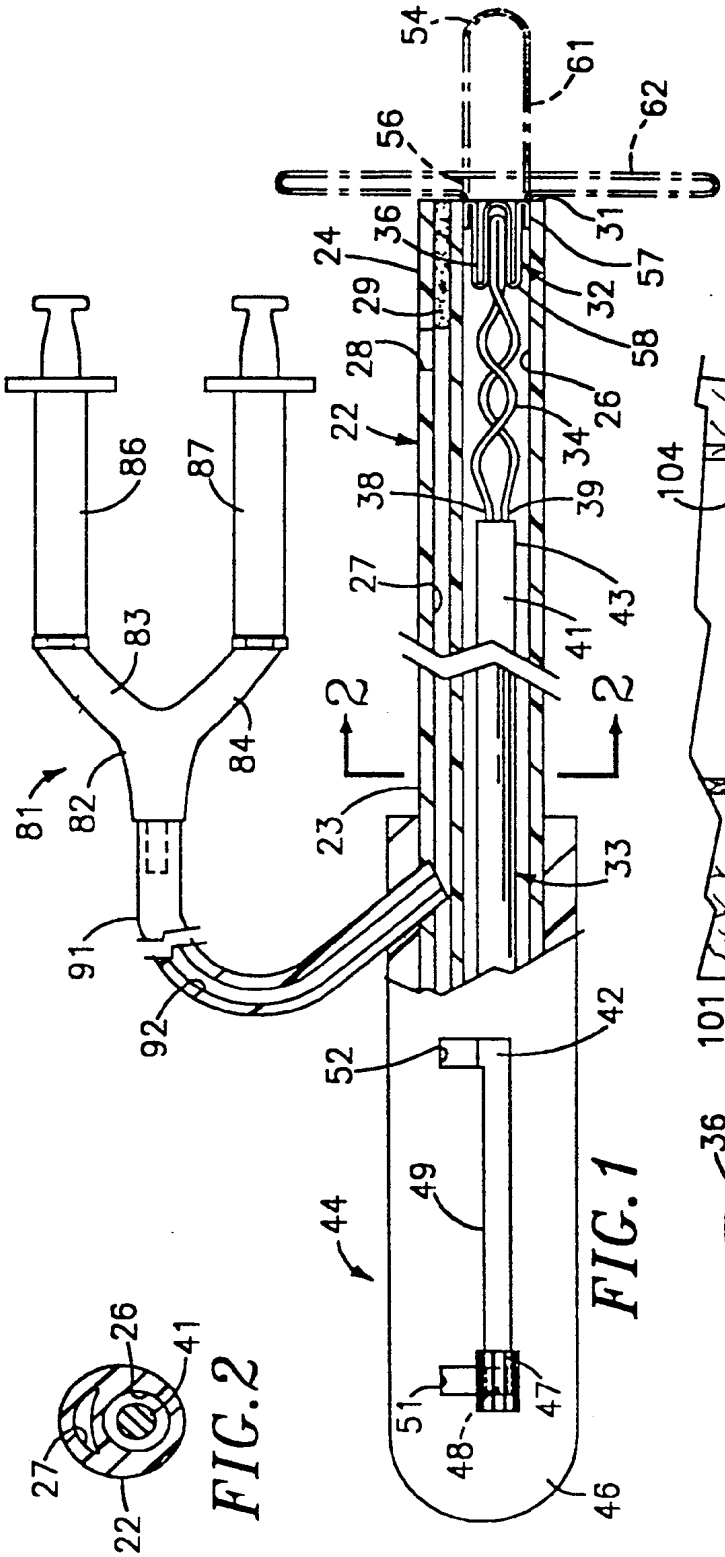

FIG. 1

FIG. 2

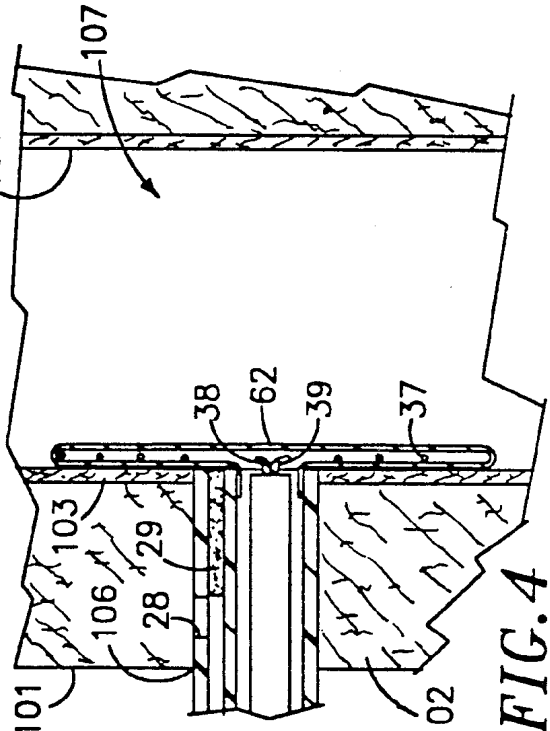

FIG. 4

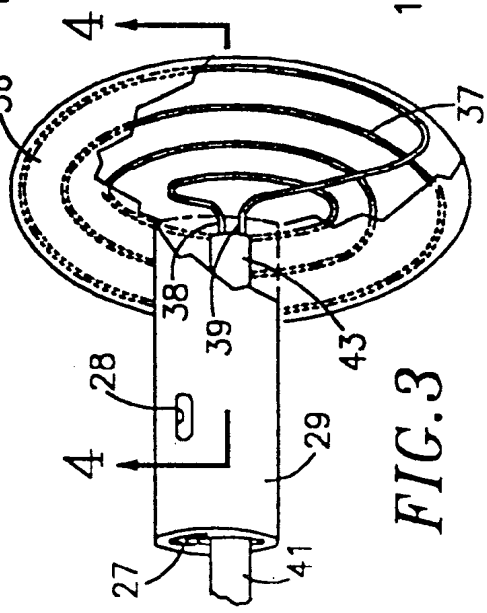

FIG. 3

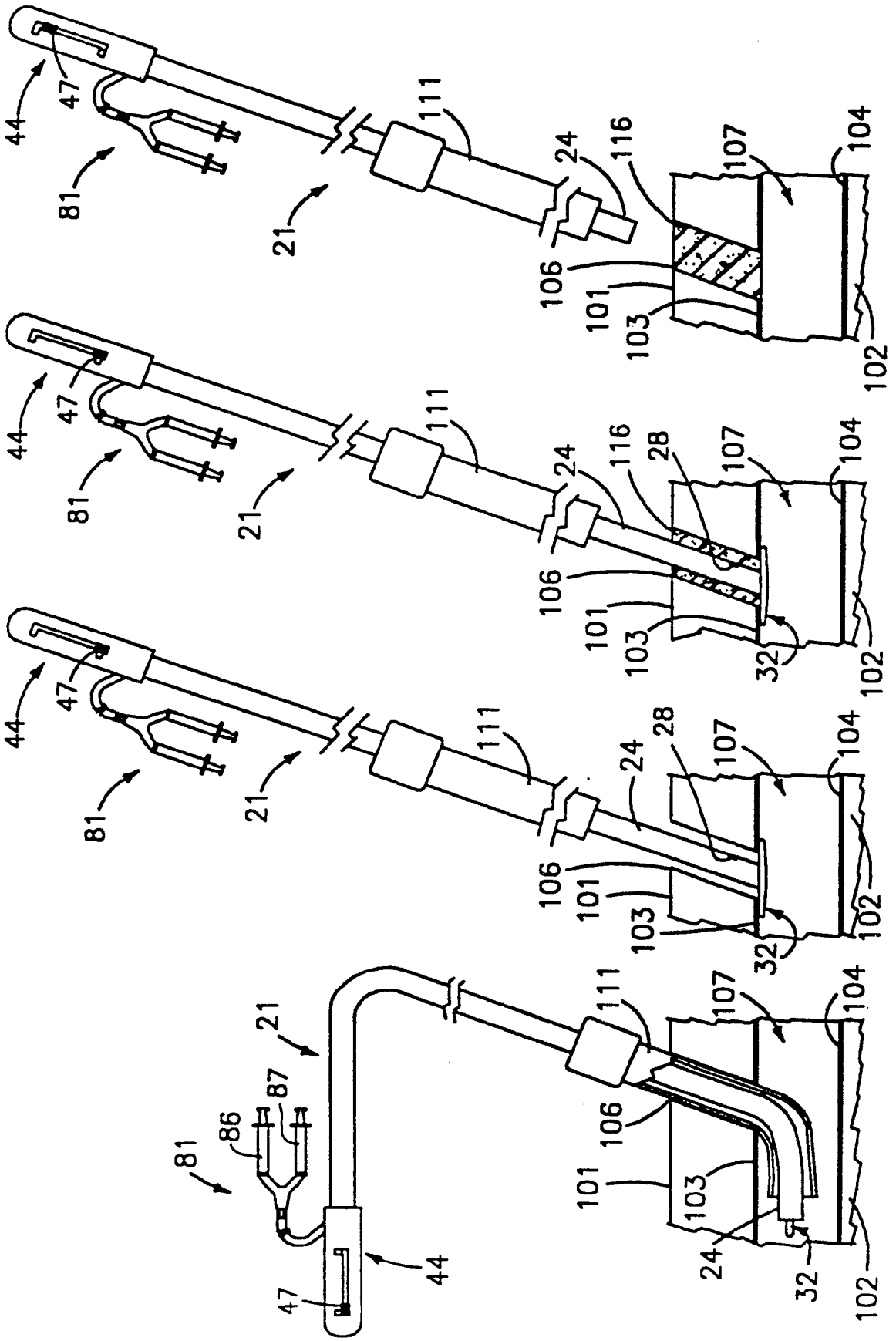

FIG.5A FIG.5B FIG.5C FIG.5D

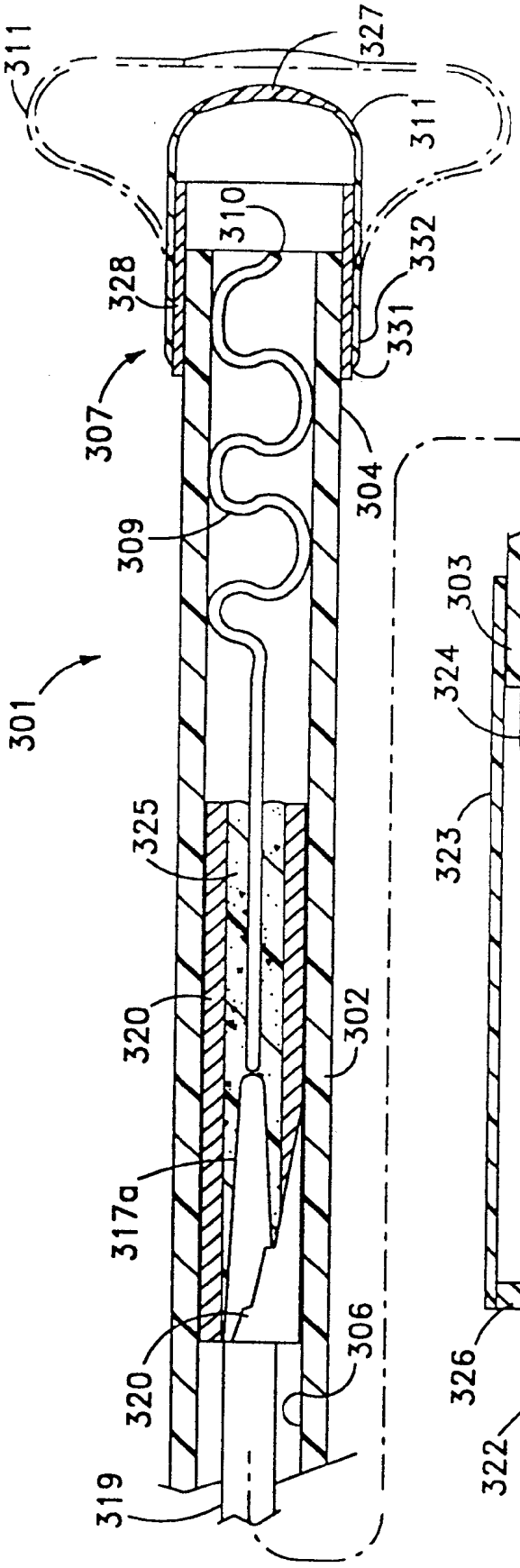
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FIG. 18

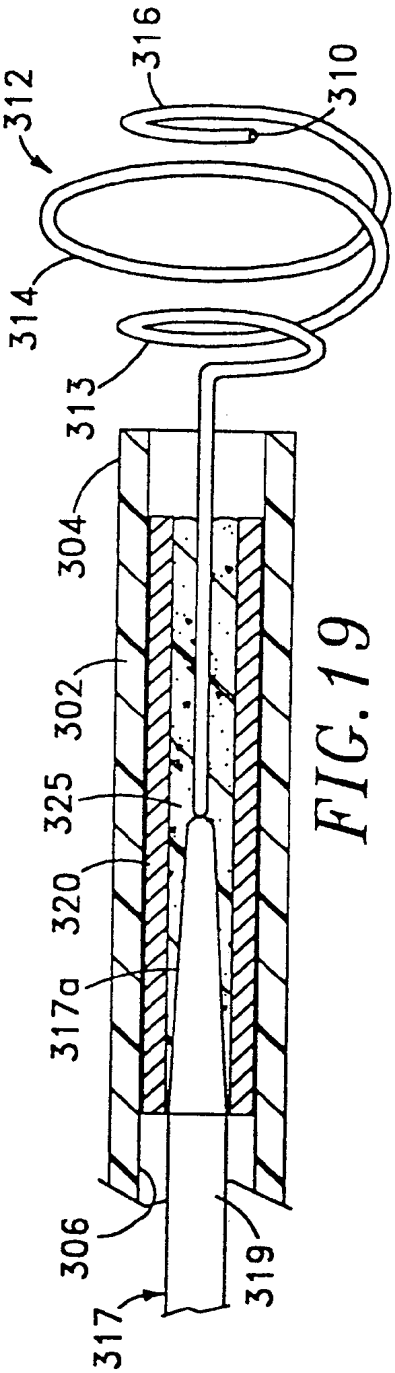
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FIG. 19

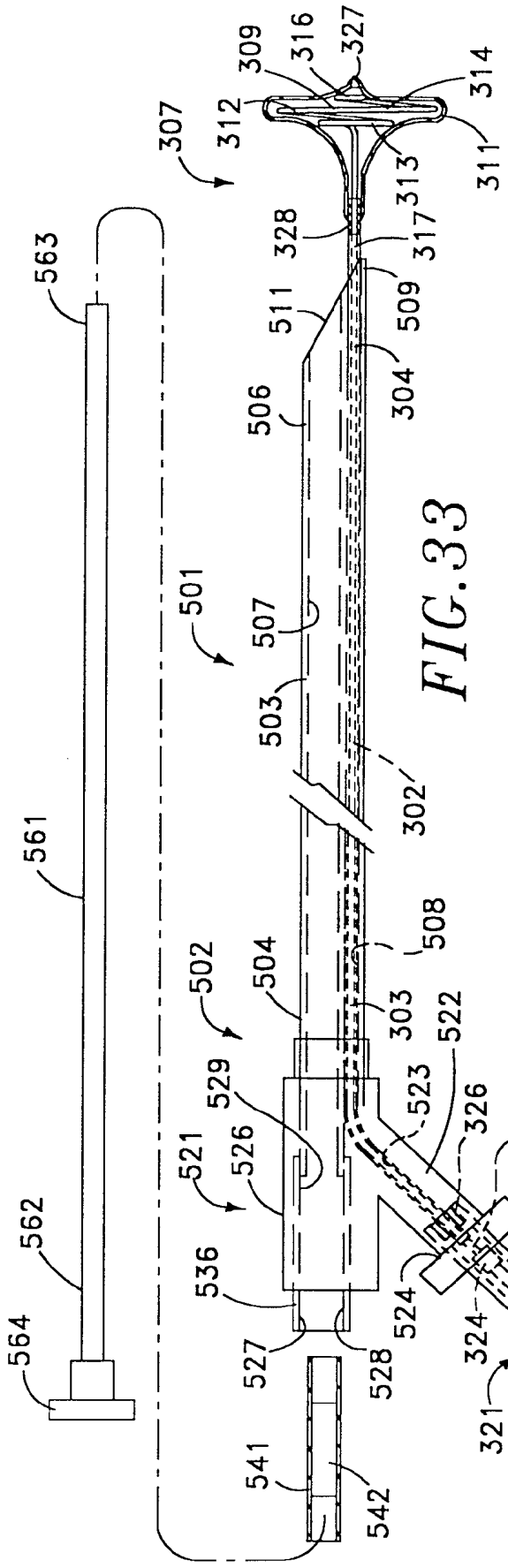
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FIG. 33

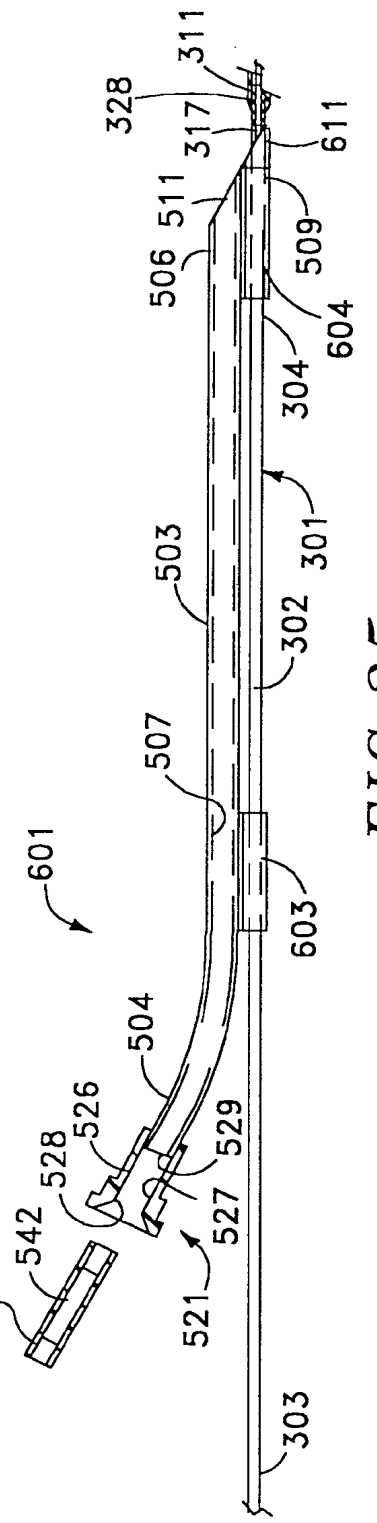
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FIG. 35

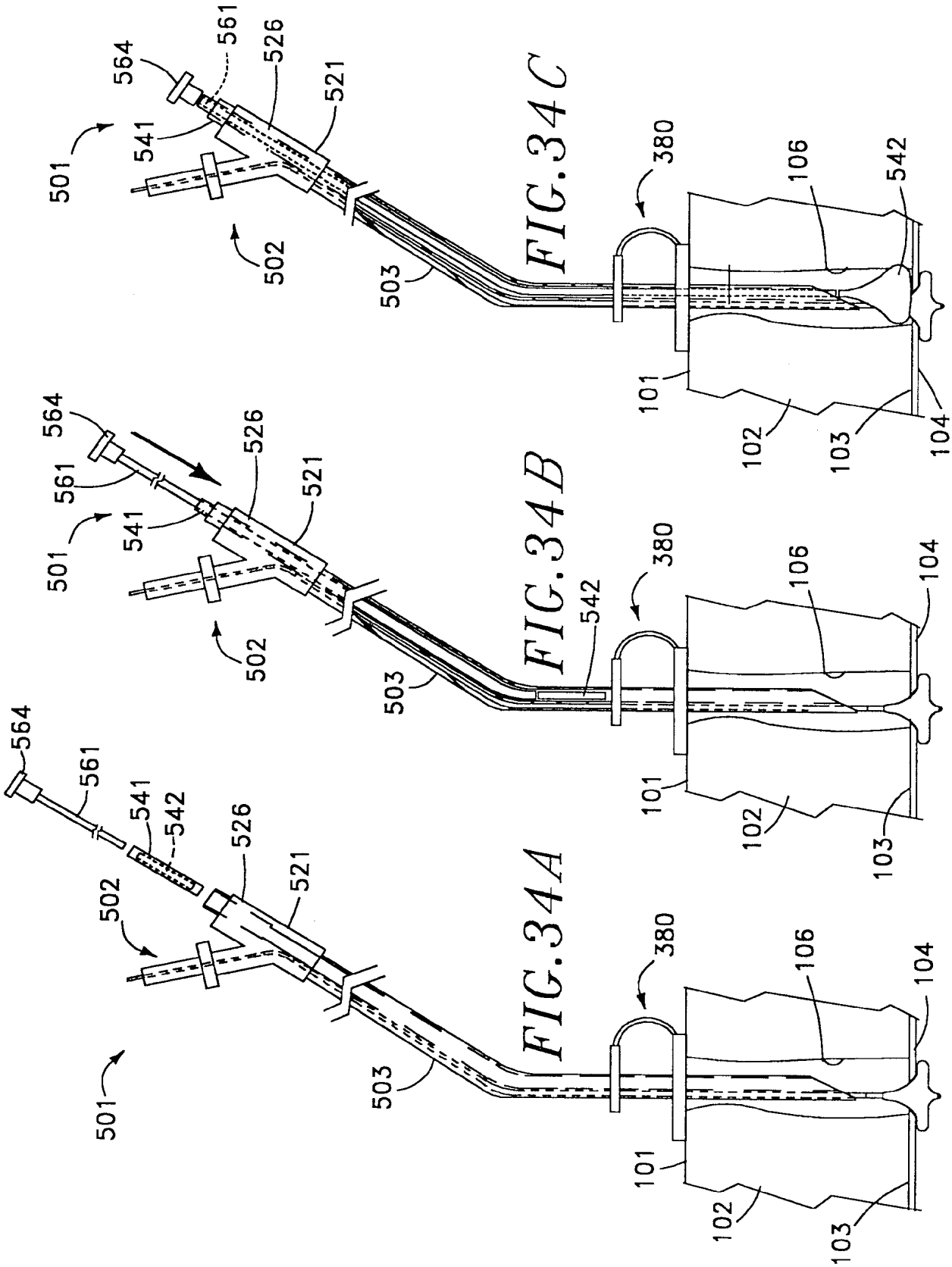

FIG.34A

FIG.34B

FIG.34C

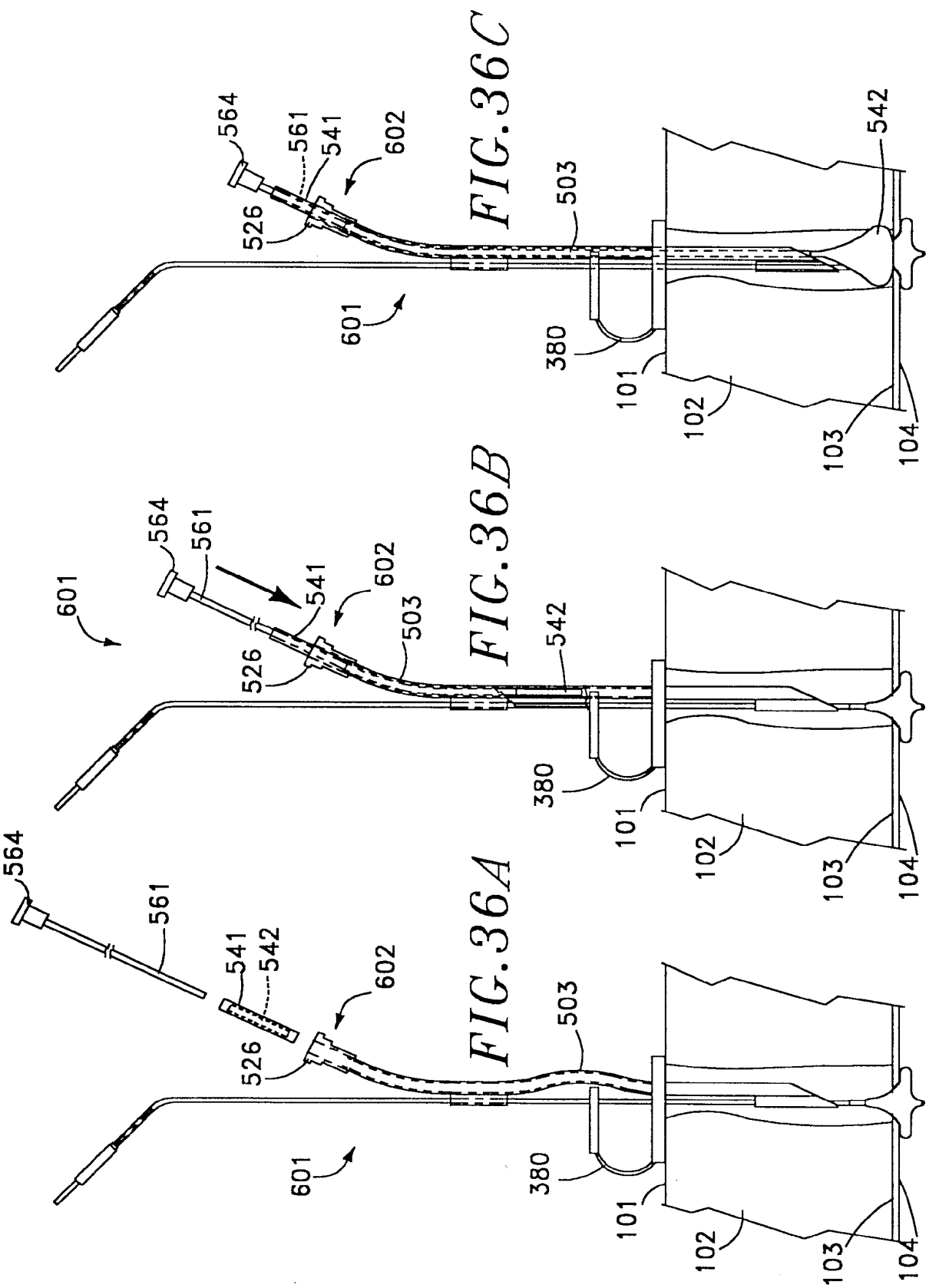

FIG. 36A

FIG. 36B

FIG. 36C

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US99/17367

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) :A61B 17/12
US CL :606/194, 213

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 604/96, 178; 606/192, 194, 213

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5,383,896 A (GERSHONY et al.) 24 January 1995, entire document.	1-12

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

*	Special categories of cited documents:	"T"	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"A"	document defining the general state of the art which is not considered to be of particular relevance	"X"	document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"E"	earlier document published on or after the international filing date	"Y"	document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"L"	document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"&"	document member of the same patent family
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"P"	document published prior to the international filing date but later than the priority date claimed		

Date of the actual completion of the international search 29 SEPTEMBER 1999	Date of mailing of the international search report 19 OCT 1999
Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703) 305-3230	Authorized officer VIKKI TRINH Telephone No. (703) 308-8238

Form PCT/ISA/210 (second sheet)(July 1992)★